

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 30 JUN 2004

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To:

see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2004/000253

International filing date (day/month/year)
22.01.2004

Priority date (day/month/year)
23.01.2003

International Patent Classification (IPC) or both national classification and IPC
C04B38/06, A61L24/00

Applicant
UNIVERSITY OF BATH

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty; inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/000253

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/000253

Box No. II Priority

1. ☒ The following document has not been furnished:
- ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).
 - ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).
- Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	4, 5
	No: Claims	1-3, 6-25
Inventive step (IS)	Yes: Claims	
	No: Claims	1-25
Industrial applicability (IA)	Yes: Claims	1-25
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V.

- 1 The following documents are referred to in this communication. Unless stated otherwise, reference is made to the passages of the Search Report.

- D1: WO 01/94274 A (UNIV LONDON ; CALLCUT SUZANNE (GB); KNOWLES JONATHAN (GB)) 13 December 2001
D2: US-A-6 136 029 (JOHNSON JAMES R ET AL) 24 October 2000
D3: WO 00/20353 A (HING KARIN ANGELA ; ABONETICS LTD (GB); BONFIELD WILLIAM (GB)) 13 April 2000
D4: WO 02/11781 A (LO WEI JEN ; ORTHOGEM LTD (GB)) 14 February 2002
D5: MILOSEVSKI M ET AL: "Preparation and properties of dense and porous calcium phosphate" CERAMICS INTERNATIONAL, ELSEVIER APPLIED SCIENCE PUBL, BARKING, ESSEX, GB, vol. 25, no. 8, December 1999 (1999-12), pages 693-696, XP004362781 ISSN: 0272-8842
D6: TANCRED D C ET AL: "A synthetic bone implant macroscopically identical to cancellous bone" BIOMATERIALS, ELSEVIER SCIENCE PUBLISHERS BV., BARKING, GB, vol. 19, no. 24, December 1998 (1998-12), pages 2303-2311, XP004168865 ISSN: 0142-9612

Process claims 1-14

Documents D1-D3, D5 and D6 all disclose so-called a slip casting processes for preparing bone substitute materials. The foam carrier can be a polyurethane film (D1, D2, D5), a wax (D6) or obtained after foaming polymeric foaming agents (D3 or D4). The subject-matter of claims 1-3 and 6-14 is thus not novel.

None of D1-D3, D5 or D6 explicitly mentions the use of a low pressure environment (e.g. present claim 5) or several immersion steps (present claim 4). The technical problem to be solved over the prior art seems to be the provision of processes yielding bone substitute materials having improved strength (see present description p. 1, I. last § - p. 3, §1). D4 however explicitly mentions that the strength of the final product can be increased if the immersion step is repeated or that the uptake of the solution of the active compound can be increased by using a vacuum. Consequently, present claims 4 and 5 do not involve an inventive step.

Product claims 15-25

Product claims 15-24 are not novel over D1-D3, D5 or D6, as the same processes as the claimed invention is used. The product features of claims 19, 20, 22 or 24 appear to be usual in the art (see Table 1, D5), and are thus also present in the products disclosed in D1-D3, D5, even if they are not explicitly mentioned.

Present claim 25 is a so-called product-by-process claim. For the assessment of novelty, the process related features are not taken into account and D1-D6 are thus anticipating this claim.